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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,138	06/23/2003	Robert Lammle	3080-5578US	1579

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EXAMINER
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TRAIL, ALLYSON NEEL

ART UNIT	PAPER NUMBER
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2876

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/602,138

Applicant(s)

LAMMLE, ROBERT

Examiner

Allyson N. Trail

Art Unit

2876

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-11 and 13-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-11, and 13-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Amendment*

1. Receipt is acknowledged of the amendment and the request for continued examination filed December 23, 2005.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 5, 9, 11, 13-17, 19, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chung (2003/0006878) in further view of Bain (2005/0021175).

Chung teaches the following in regards to claims 1, 11, 13, and 14:

Chung teaches a method for providing pharmaceutical information to a patient.

The method of providing information includes dispensing a pharmaceutical product having an electronically identifiable tag associated with the product.

Specifically, Chung discloses in paragraph 0141, when filling a prescription, a smart tag reader at the pharmacy or other dispenser reads the prescription smart tag 410 and produces or generates a pick list 410 from which a pharmacist or other dispensing agent can fill the prescription. The pharmacy fills the prescription and labels 420 each item dispensed with a smart tag in which is stored the medication and prescription information. The pharmacy also applies a conventional human-readable printed label which may also include bar-coded information.

In paragraph 0142, Chung teaches the medication smart tag and prescription smart tag being read and cross checked 430 for completeness and accuracy. Such reader maybe linked to access 440 a relational database for comparing the information read from the smart tags with a medical database for verifying and/or identifying allergy, drug interaction, diagnostic or other information.

With respect to claims 5 and 15, Chung teaches using a display 50 (touch screen display 50) for providing an easy to use and convenient combined display 50 and input means 52 through which information may be provided and information and requests may be received. (See paragraph 0086).

Chung teaches the following in regards to claims 16, 19, and 23:

"Suitable relational database software include ACCESS and SQL Server database software which runs on conventional PC processors with standard operating systems, such as Windows-NT, both available from Microsoft Corporation of Redmond, Wash., as well as the ORACLE, SYBASE and INFORMIX database software. Preferably the database software is "Internet-ready" in that it includes features facilitating connection to and communication of information via the Internet." (Paragraph 0108).

Chung teaches the following in regards to claim 17:

"Desirably, processed information and/or transactional information should be available in human readable form, such as by display on a computer monitor or by print out by a computer printer, both of which may be conventional." (Paragraph 0093).

"In a simplified database, database 1240' includes, for example, lists 1242, 1246 and 1248. This database arrangement may be advantageous where the database is stored in a local processor and/or a smart tag reader/writer where available memory capacity may be more limited than in another processor. In either a complete or simplified database, information relating to each writing of information to each smart tag is communicated to a processor in real time or delayed, and may be periodic or aperiodic. Information may be communicated by any of the means described as well as by manual communication, e.g., by transporting the smart tag reader/writer and/or local processor and/or computer media containing the information stored in such smart tag reader/writer and/or local processor to another processor." (Paragraph 0107).

Teachings disclosing the limitations of claims 21 and 22 are found above. Specifically, Chung teaches a computer processor for accessing a database including information regarding prescriptions and medications. It is inherent for the computer processor to run on a software program.

Chung's teachings above fail to teach both audibly disclosing the stored pharmaceutical information to a patient and additionally, including prescription counseling, and prompting the patient with an opportunity to accept or decline the counseling by interacting with an electronic input device.

Bain teaches the following in regards to claims 1, 9, 21:

"An automated prescriptions dispensing system includes a patient interface portion, a dispensing portion and a control portion." (Abstract).

Bain teaches electronically disclosing the stored pharmaceutical counseling either visually and/or audibly to the patient.

Specifically, Bain teaches in paragraph 0020, a patient interface portion, which includes a display screen that conveys information to the patient. The information includes counseling information regarding the medication and potential side effects and/or drug interactions. Bain teaches that the counseling may either be in printed text, or a video of a pharmacist explaining proper use of the medication. A printer may also be provided for printing counseling or other information for the patient to take. Lastly, Bain teaches that a speaker may also be provided for giving counseling information to those who are visually impaired.

In view of Bain's teachings, it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to combine Bain's teachings of generating an audible message when scanning a product with Chung's teaching of disclosing medical product information to a patient when the product's tag has been read. Additionally, one would be motivated to offer prescription counseling when desired by the patient, when picking up prescriptions at the pharmacy. Chung teaches producing an alarm (paragraph 0058) when the patient should be warned that the medication scanned is not for them. One would be motivated to additionally include prescription counseling in cases where the patient needs to be warned about certain medications. This way, patients will have a clear warning of dangerous medication interaction or side effect that the medication may cause.

4. Claims 2, 6, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chung (2003/0006878) in combination with Bain (2005/0021175) and in further view of Catan (2002/0143860).

Chung's teachings in combination with the teachings of Bain are discussed above. The combination fails to teach prompting the user with a first message, wherein the message provides the user with an interactive choice of accepting or declining information about a scanned product or creating an electronic log of the patient.

With respect to claim 2, Catan teaches providing a message to the user, which gives the user an interactive choice of accepting or declining information about a scanned product. Specifically, when data is stored by a reader, the user is prompted to accept a message from the network server 140, and upon acceptance, the message is delivered at concurrently or at a later time.

Catan teaches the following in regards to claim 6:

"The identification of discriminants is a well-developed technology in itself. A very simple approach is to generate a histogram that indicates the terms that appear most often in the returned records and to allow the user to select from among the terms with the highest frequency." (Page 16, paragraph 0153).

Catan teaches the following in regards to claim 10:

Figure 1 shows the portable reader 100. The portable reader includes a display where messages are shown.

In view of Catan's teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Catan's method of prompting the user

with a message in order to receive a command to disclose product information along with the teachings of Chung and Bain. The combination of Chung and Bain teachings above, disclose a method for generating an audible message and prescription counseling for a patient in order to avoid the possibility medication interactions. Both Catan and the combination of Chung and Bain teach offering beneficial information to a user. Although Catan's invention does not specifically deal with pharmaceutical products, the invention is geared towards a label reader. One would be motivated to use Catan's method of waiting for a user command in order to avoid wasting the time of a user who is not in need of the product information.

5. Claims 7, 20, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chung (2003/0006878) in combination with Bain (2005/0021175) and in further view of Stewart (2003/0183683).

Chung's teachings in combination with the teachings of Bain are discussed above. The combination fails to teach recording an electronic signature of the patient.

With regards to claims 7, 20, and 24, Stewart teaches in figure 5, a digital signature capture means or signature pad 510. The pad is coupled to the computer means 504 and is used to capture the signature of the donor, collector, or other personnel.

In view of Stewart's teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Stewart's digital signature capturing device in combination with the teachings of Chung and Bain. One would be motivated



to additionally include an electronic signature capturing device in order to authenticate the patient before administering the prescription.

6. Claims 3, 8, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chung (2003/0006878) in combination with Bain (2005/0021175) and Catan (2002/0143860) and in further view of Kaafarani et al (2004/0078237).

Chung's teachings in combination with the teachings of Bain and Catan's teachings are discussed above. The combination fails to allow the patient the interaction option of speaking to the pharmacist.

With respect to claims 3, 8, and 18, Kaafarani et al teaches in paragraph 0020, providing the patient an optional step of dialing direct from the module to speak with a customer service representative or, if necessary, to speak with a pharmacist or pharmacy technician.

In view of Kaafarani et al's teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to give the patient the option of speaking to the pharmacist. Although the automatic or commanded information is beneficial, the patient may additionally have questions for the pharmacist. One would be motivated to include the option of speaking to the pharmacist for the above reason.

7. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chung (2003/0006878) in combination with Bain (2005/0021175) and in further view of Young et al (5,353,121).

Chung's teachings in combination with the teachings of Bain are discussed above. The combination fails to teach storing the selection of the user.

Young et al teaches the following in regards to claim 25:

Claim 1, which discloses "a memory, coupled to said user selection input means, for storing said user selections".

In view of Young et al's teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to include in the customer interface taught by Bain the function of storing the user's selection as taught by Young et al. One would be motivated to store the user's selection regarding accepting or declining prescription information in order to ensure that the pharmacy is not liable for misuse of medication.

8. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chung (2003/0006878) in combination with Bain (2005/0021175) and in further view of Wallace et al (2004/0210341).

Chung's teachings in combination with the teachings of Bain are discussed above. The combination fails to specifically teach that the counseling complying with state law.

Wallace et al teaches the following in regards to claim 26:

"Per the regulations, "complimentary starter dose" means a prescription drug packaged, dispensed, and distributed in accordance with state and federal law that is provided to a dispensing prescriber free; of charge by a manufacturer or distributor and dispensed free of charge by the dispensing prescriber to his or her patients."  
(Paragraph 0274).

In view of Wallace et al's teachings it would have been obvious to one of ordinary skill in the art at the time the invention to ensure that the counseling taught by Bain is in compliance with state law as is taught by Wallace et al. One would be motivated to comply with state laws in order to ensure that the safety of the patient is a top priority.

### ***Response to Arguments***

9. Applicant's arguments filed June 3, 2005 have been fully considered but they are not persuasive. Applicant's argue that publications, not issued patents, are not available under 35 U.S.C. 103. This argument however is not correct. Disclosed below is statement of statutory basis for a 102(e), which clearly states that claims may be rejected by a published application for patent:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Therefore, prior art used with a 102(e) rejection may also be used for a rejection under U.S.C. 103.

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

### ***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Allyson N. Trail* whose telephone number is (571) 272-2406. The examiner can normally be reached between the hours of 7:30AM to 4:00PM Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Lee, can be reached on (571) 272-2398. The fax phone number for this Group is (571) 273-8300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [[allyson.trail@uspto.gov](mailto:allyson.trail@uspto.gov)].

*All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.*

Allyson N. Trail  
Patent Examiner  
Art Unit 2876  
February 28, 2006



KARL D. FRECH  
PRIMARY EXAMINER